DEC 2 0 2000

IN-LINE DIAGNOSTICS

510(k) SUMMARY

SECTION 1 – GENERAL INFORMATION

1. **Applicant/Specification Developer:**

In-Line Diagnostics
695 North 900 West
Kaysville, UT 84037
Tel: (801) 451-9000
Fax: (801) 451-9007

Registration Number: 1721979

2. **Contact Persons:**

Mr. Matthew L. Haynie
Dir. of Quality Assurance/Reg. Affairs

3. **Administrative Information:**

a. **Trade/Proprietary Name Including Model Number of Devices:**

CRIT-LINE MONITOR III With TQA (CLM III_{TQA})

b. **Common Name or Classification Name (21 CFR Part 807.87) of Device:**

Non-invasive Hematocrit, Blood Volume, Oxygen Saturation, Recirculation and Access Blood Flow Monitor

c. **Address of Manufacturing Facility/Sterilization Sites:**

In-Line Diagnostics
695 North 900 West
Kaysville, UT 84037

Contract Manufacturers:

BSD Medical (Monitor Assembly)
2188 West 2200 South
SLC, UT 84119

Phone: 801-972-5555
Fax: 801-972-5930

The CLM III_{TQA} is a non-sterile product.

d. Class in which Device has been placed:

Class II

e. Reason for Pre-market Notification

To claim that the CLM III_{TQA} can transcutaneously (i.e. through the skin) estimate access blood flow (ABF), which is the rate at which blood is flowing through a dialysis patient's access site. Access blood flow is a key indicator of an access site's condition (i.e. how deteriorated or blocked that site has become over time). This test can be performed just prior to, during, or just after hemodialysis treatments depending on which technique is used as described within this submission.

NOTE: ***The CLM III_{TQA} already estimates ABF via the measurement of absolute hematocrit and changes to absolute hematocrit. This delta hematocrit or "ΔH" technique requires the use of a transparent viewing window as well as the reversal of the arterial and venous lines. The transcutaneous method, however, is designed to estimate ABF through the skin directly over the access shunt without the use of a viewing window or reversal of the arterial and venous lines. In addition, the transcutaneous method will yield an accurate result within approximately 1 minute as opposed to 20 minutes, which is a substantial improvement for both the patient and the dialysis clinician.***

f. Identification of Legally Marketed Device Which We Claim Substantial Equivalency

There are 3 predicate devices to which substantial equivalence is being claimed. These devices are as follows:

1. Transonic HD01 Monitor (# K960817)
   The Transonic HD01 Monitor estimates ABF by saline dilution and transit-time ultrasound principles. All in-vivo, clinical, transcutaneous ABF data that was gathered with the CLM III_{TQA} was compared to ABF data estimated by the Transonic HD01 Monitor. All in-vivo ABF tests comparing the two devices were taken one after the other to insure as accurate a comparison as possible.

2. Crit-Scan II Monitor (#K983551)

   The CRIT-SCAN II Monitor transcutaneously measures absolute hematocrit (i.e. the measured value is a real and final value and requires no calibration or reference adjustment). This technology is referenced as a predicate device because the theory of operation of the CLM III_{TQA} for the transcutaneous measurement of the changes in the hematocrit from which

ABF is estimated is based on the theory of operation of the CRIT-SCAN II. Also, the optical components used in the CLM III_{TQA} are the same as those used in the CRIT-SCAN II.

3. Crit-Line III Monitor (#K992227)

The Crit-Line III Monitor is a legally marketed device for the estimate of ABF via measured changes in absolute hematocrit (ΔH) as they occur in the extra-corporeal dialysis delivery circuit. This technology is referenced as a predicate device because the theory of operation of the CLM III_{TQA} when used in the transcutaneous estimate of ABF is based on the same principle of relative change in measured hematocrit.

g. Compliance with Requirements of the Federal FD&C Act:

The Gastrointestinal and Restorative Device (DGRD) Panel has classified this device as Class II, 21 CFR Part 876.5820

SECTION 2 – INTENDED USE

The intended use of the CLM III_{TQA} is as a non-invasive hematocrit, oxygen saturation, blood volume, recirculation and access blood flow device.

NOTE: All of these intended uses have already been 510 (k) approved. The additional intended use that is being claimed in this submission is for the transcutaneous estimate of Access Blood Flow (ABF). The currently approved predicate method for ABF estimate using the CLM III_{TQA} ***is via detected changes in absolute hematocrit in the extra-corporeal dialysis delivery circuit and requires the use of a transparent viewing window as well as the reversal of the arterial and venous lines. The subject transcutaneous method of estimating access blood flow requires the placement of an optical sensor on the skin directly over the access site in order to detect relative changes in hematocrit occurring in the blood flow. These changes in relative hematocrit occur as a result of a saline bolus, which may be injected into the arterial or venous lines, upstream of the optical sensor.***

SECTION 3 – DEVICE DESCRIPTION

The CLM III_{TQA} non-invasively measures hematocrit, oxygen saturation and % change in blood volume. The CLM III_{TQA} also estimates access recirculation and Access Blood Flow. The optical light emitted by the device sensor is back scattered by the constituents of the blood and the surrounding tissue. The hematocrit measurements from which the transcutaneous ABF value is estimated is a result of how the absorbed and scattered light is detected and processed once it has passed through the tissue, blood, and skin. The information below is specific

to the CLM III_{TQA}'s ability to transcutaneously measure changes in the hematocrit and from thence, estimate Access Blood Flow.

The CLM III_{TQA} gathers information about the hematocrit of the blood flowing through the access via an optical sensor that is placed directly over the access shunt of the patient. Light is emitted into the patient's access area from a matrix of light emitting diodes and the back scatter due to the absorption and scattering of that light in the tissue is received by detector photodiodes placed at known distances from the LED's. The degree of back scattering and absorption directly affects the amount of light that is reflected back to the detector and is a function of the bulk attenuation coefficient or "alpha values" of the tissue, blood and skin. This alpha value is mathematically directly proportional to the hematocrit of the blood flowing through the patient's access.

If the hematocrit of the blood flowing through the access is changed in some manner, (i.e. as a result of a saline bolus being injected into the access site and thereby diluting the access hematocrit) the access site alpha value measured by the CLM III_{TQA} sensor will dramatically change.

By base-lining the alpha value of the access area prior to injecting the bolus, then measuring the change of hematocrit in the access area as the bolus passes through the access, the CLM III_{TQA} is able to accurately determine the percentage change in hematocrit of the access blood flow. Using the FICKE principle and by knowing the volume of the bolus injected into the access and measuring the percentage change in hematocrit, the access blood flow can be directly computed. Because this is an application of FICKE's law in a closed system, flow elements such as the dialysis pump speed and injection rate do not affect the measurement of changes in the hematocrit or the resultant calculation of ABF.

All optical components in the sensor pad which are used in making the transcutaneous estimate are identical to those already in use in the current CLM III. The only variation is in the orientation of the emitting diodes and detectors in a unique sensor pad, which is made of a commonly used urethane foam designed to contact the skin in a manner typical of pulse oximetry. The emitting diode and detectors are mounted within a planar, flexible sensor. The flexibility of the sensor allows it to be placed directly over and on the access area, and allows it to conform to that area, thus maintaining contact with the skin. Modulated light is emitted from the LED's into the tissue, back scattered, and detected by the sensor photodiode in exactly the same manner as pulse oximetry – which was the original predicate of the Crit-Line. Detected modulated light is then filtered, processed, and used in algorithmic computations to yield a change in hematocrit, and ultimately to calculate an ABF value. All circuitry used to perform these functions within the sensor pad is identical to that currently found and used in the CLM II. The sensor elements are also identical to those of the CRIT-SCAN II.

As stated above, the optical system measures the percentage change in hematocrit flowing through the access site. This percentage change is a function of the proration of the volume of the access to the total volume of tissue (including the access shunt itself) that is illuminated by the optical pad. For this reason, the sensor is placed directly over the shunt. Because the measurement is a "percentage change" as opposed to an "absolute value", variations in shunt diameter, location and size become immaterial in the computation of ABF. It is only necessary that the access shunt be contained within the illuminated volume of the optical pad. This concept differs from the previously approved CRIT-SCAN II (#K983551) which measures an absolute hematocrit value and requires a normalizing component in its more advanced computations. In the subject device method, no normalizing component is required. The percentage change in hematocrit (as opposed to an absolute value) by definition is self-normalized.

The subject device used a primary LED of 830nm wavelength. Its 830nm-opto signal has been shown in our previous submissions to not be significantly affected by skin color (i.e. melanin, O2 Saturation, etc) or by other extenuating issues with the tissue (see Submission # K983551). This has been re-verified and is demonstrated in the in-vivo clinical data that is included in this submission.

SECTION 4 – COMPARATIVE INFORMATION

a. Discussion of Similarities and Differences:

CLM III_{TQA} vs. HD01

Although the CLM III_{TQA} and the Transonic HD01 method for measuring ABF produced substantially equivalent results, the two methods are different in that the CLM III_{TQA} transcutaneous method estimates ABF via the measurement of hematocrit change over a very short period of time. The Transonic HD01, on the other hand, estimates flow density using saline dilution and ultrasound principles.

In order to estimate ABF with the Transonic HD01, the two blood lines are reversed at the point where the two hemodialysis needles are connected to the hemodialysis blood lines or dialysis delivery circuit, employing the flow clamps present on the lines in standard patient care protocol. The HD01 access flow method requires an injection of about 10 ml of 0.9% saline in the venous blood line injection port before the bubble trap. The venous sensor then records a dilution curve in response to the injection. The injected bolus then enters the patient via the arterial needle, which must be placed facing upstream in the artery to assure complete mixing. The venous needle samples the saline bolus concentration in the mixed blood stream. Next, the arterial line sensor registers its saline bolus dilution curve. The HD01 estimates ABF from the ratio of these two saline-induced dilution curves factoring in the instantaneous blood flow that must also be estimated in the procedure.

CLM III_{TQA} vs. Crit-Scan II

The CLM III_{TQA} uses the same opto-electronic components as the CRIT-SCAN II (See #K983551). The major difference between the two devices is from an ergonomic/packaging standpoint. The Crit-Scan II uses a "pillow block" design that fits firmly around the finger and, in addition to optical data typical of both devices, also measures volumetric changes in the finger tip with each cardiac cycle. This pillow block design contains all the necessary optical and electronic components necessary for absolute hematocrit measurement. The CLM III_{TQA}, on the other hand, uses a sensor pad that is placed directly on the skin directly above the access and approximately 1 ½ inches downstream of the venous needle. This design allows for the measurement of the relative change in hematocrit from which ABF may be estimated.

b. Comparative Performance Evaluation:

IN-VIVO ANALYSIS

Between April 22, 2000 and June 1, 2000, 72 data points were clinically gathered in-vivo on 59 patients comparing the CLM III_{TQA}'s transcutaneous readings to the HD01 Monitor. If more than one data point was gathered on the same patient, the data was gathered on a different day (i.e. no two data points were ever gathered on the same patient on the same day).

The transcutaneous data was gathered using two different methods. The methods are only different in that they allow for various means of bolus injection into the access. Otherwise, these methods produce exactly similar results. The reason why two different methods were validated is to provide flexibility to the Renal Care Clinician as to when or how the test may be performed. As a result of these two methods, the transcutaneous ABF estimate can be made just prior to the dialysis treatment, during the dialysis treatment, or just after the dialysis treatment. The following is a brief description of these methods:

1. **The "Arterial Needle Flush" Method (Pre/Post Treatment)**
   This method can be performed prior to the dialysis treatment or just after the completion of a dialysis treatment. When this method is used, a 30 cc bolus (10 cc to clear the needle line, 20 cc of actual bolus) of Normal Saline is injected into the arterial line once the optical sensor pad has been properly placed over the access site. This injection is made after the arterial and venous needles have been inserted into the site and clamped off, but before dialysis has been initiated. This method can also be performed post treatment, prior to needle removal and after dialysis lines have been disconnected from the needles.

2. **The "Venous Port Injection" Method (Intra-Treatment)**
This method is performed any time following the initiation of the hemodialysis treatment. When this method is used, a 30 cc bolus of Normal Saline is injected into a venous port of the dialysis delivery circuit once the optical sensor pad has been properly placed over the access site. The venous port is used in this method so that the bolus passes directly into the access as opposed to passing through the entire delivery circuit before entering the access.

The following is a breakdown of the 72 data points, which were gathered:

a. Sex: Test population consisted of 42 males and 17 females. Of the total data: 47 data points were gathered on males and 25 data points on females. During the study, no ABF dependence was noted based on sex.

b. Age: The youngest subject tested was 19 years old while the oldest subject was 84 years old. IDC did not perform any pediatric tests or any tests on subjects less than 19 years old. During the study, no ABF dependence was noted based on age.

c. Access Type: 25 patients had native fistulas (an artery surgically connected to a vein) and 34 patients had Gor-Tex PTFE grafts. As far as total tests performed: 27 tests were taken on native fistulas and 45 tests were taken on Gor-Tex PTFE grafts. No ABF dependence was noted based on the type of patient access or access material.

d. Skin Pigmentation: 42 patients were White, 5 patients were Black and 12 patients were either Asian, Hispanic or Native American. As far as total tests performed: 46 tests were performed on White patients, 8 tests were performed on Black patients and 18 tests were performed on Asian, Hispanic or Native American patients. No ABF dependence was noted based on skin pigmentation.

e. ABF Range: ABF results were comparable to the Transonic HD01 within a range as low as 153 ml/min and as high as 2042 ml/min. This range is very typical of the ABF values that are measured/estimated in the standard hemodialysis environment.

f. Shunt location. 22 patients had accesses located in the upper arm, 35 patients had accesses located in the lower arm and 2 patients had accesses located in the leg. As far as total tests performed: 28 tests were performed on accesses located in the upper arm, 41 tests were performed on accesses located in the lower arm and 3 tests were performed on accesses located in the leg. During the study, no ABF dependence was noted based on access location.

g. User Dependencies: It was noted that the CLM III_{TQA} was sensitive to patient movement. Therefore, patients were asked to remain still and to not eat during the 1-minute data acquisition phase. In addition, it is recommended that no blood pressure test take place during the ABF test.

After all 72 data points were gathered, a regression analysis was performed to compare the CLM III_{TQA} ABF readings to the Transonic HD01 ABF readings. A comparison of the data resulted in a correlation coefficient of .974 and a standard deviation of 95 ml's per minute.

IN-VITRO ANALYSIS

In addition to the in-vivo data that was gathered, 28 data points were gathered comparing both the CLM III_{TQA} Transcutaneous ABF readings to a calibrated blood pump delivering a known access blood flow. In addition, 14 data points were gathered comparing the HD01 ABF readings to a blood pump delivering a known access blood flow.

An in-vitro cardiovascular-dialysis model was constructed to test Transcutaneous ABF using a 1L central blood volume, a 4L venous pool, and a PTFE access covered with chicken skin. A typical arterial-venous dialyzer circuit with dialyzer pump was connected to the access simulating hemodialysis treatment conditions. While the cardiac output pump (Qh) was running at 3 L/min, an access (Qa) pump was varied from 300 to 2200 ml/min. A small 25 x 30 mm transcutaneous sensor was placed on top of the chicken skin directly over the access to measure the Hct, approximately 25mm downstream of the venous needle and a single 5 cc bolus of saline of predetermined volume (Qi) was infused directly into the access. Mass balance requires that Transcutaneous Access = Access Blood Flow = $Qi/(\Delta Hct/Hct)$.

The in-vitro data taken with a 30 ml bolus of saline resulted in the CLM III_{TQA} Transcutaneous readings having a standard deviation of 33ml/min and a coefficient of variation (i.e. relative error) of .04 when compared to a known ABF delivered by a calibrated reference pump. The in-vitro data also resulted in the Transonic HD01 Monitor having a standard deviation of 24 ml/min and a coefficient of variation (i.e. relative error) of .02 when compared to a known delivered ABF by the same calibrated reference pump..

Both the in-vivo and in-vitro data indicate that the CLM III_{TQA} and the Transonic HD01 are substantially equivalent in the estimate of ABF.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2000

Mr. Matthew L. Haynie
Director of Quality Assurance/Regulatory Affairs
In-Line Diagnostics Corporation
695 North 900 West
KAYSVILLE UT 84037-4118

Re: K001763
Crit-Line III TQ_A Monitor
Dated: September 18, 2000
Received: September 21, 2000
Regulatory Class: II
21 CFR §876.5820/Procode: 78 MQS

Dear Mr. Haynie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K001763

Device Name: CRIT-LINE III TQA MONITOR

Indications for Use:

The intended use of the CRIT-LINE III TQA Monitor is as a non-invasive hematocrit, oxygen saturation, and percent change in blood volume monitor. The CRIT-LINE III TQA Monitor also non-invasively estimates access recirculation and non-invasively estimates access blood flow.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription for Use ✓ OR Over the Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001763